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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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| Serial No.: | 10/619,985 | |
| For: | A Device and Method to Limit Filling of the Heart | Examiner: Bruce Edward Snow |
| Applicant: | Thomas David Starkey | |
| Filing Date: | July 15, 2003 | |
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Alexandria, VA 22313-1450



## BRIEF FOR APPELLANT

Appellant hereby appeals from the final rejection of the above-identified application, the rejection being set forth in the Final Office Action mailed on February 3, 2005. A Notice of Appeal from the final rejection was timely filed on June 2, 2005. For the reasons discussed in detail hereinbelow, Appellant respectfully requests that the Board of Patent Appeals and Interferences reverse the rejection.

Appellant's brief is submitted herewith in triplicate. Submitted herewith is the fee set forth in 37 C.F.R. § 41.20(b)(2) of $250. The Commissioner is authorized to charge any deficiency or credit any overpayment associated with the filing of this Appeal Brief to Deposit Account 23-0035.

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## I. Real Party in Interest

Thomas David Starkey is the real party in interest.

## II. Related Appeals and Interferences

To the best of Appellant's belief, Appellant does not know of any other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

## III. Status of Claims

The following is the status of all claims in the application. Claims 1, 5, 8-11, 14-16, 18-21, and 29-31 are rejected. Claims 32-34 are allowed.

The appealed claims are Claims 1, 5, 8-11, 14-16, 18-21, and 29-31, which are set forth in the Appendix section of this Brief.

## IV. Status of Amendments

No amendments have been filed subsequent to final rejection.

## V. Summary of Invention

The following is a summary of the invention defined in the claims involved in this appeal. The invention described in this application pertains to the class of medical devices used to treat heart disease that function to decrease the size of the heart, or to prevent enlargement of the heart.

The invention described in this patent application is a device used to treat heart disease by decreasing the size of a diseased heart, or to prevent further enlargement of a diseased heart. The device works by limiting the volume of blood entering the heart during each cardiac cycle. The device partitions blood within the heart, and protects the heart from excessive volume of blood and the associated pressure from an excess volume of blood. This new invention is placed within the interior of the heart, particularly within the left ventricular cavity. The device is a hollow sac with two openings. The sac simulates the shape and size of the interior lining of a normal heart. It allows the heart to fill through one opening juxtaposed to the annulus of the mitral valve to a predetermined, normal volume, and limits filling of the heart beyond that volume. It then allows blood to be ejected easily through the second opening through the aortic valve. By limiting the amount of blood entering the heart, the left ventricle is not subjected to the harmful effect of excessive volume and pressure of blood during diastolic phase, the period of the cardiac cycle when the heart is at rest. This allows the heart to decrease in size, or to reverse remodel, and to recover lost function. ('985 Application, p. 9).

The first component of the invention, a diastolic volume limiting apparatus ("divola") is shown in Figs. 1 and 2. Fig. 1 depicts a divola **20** in a frontal view, and Fig. 2 depicts a divola **20** in a left side view. An inflow orifice **22** is an opening that allows blood to enter the divola. An inflow tract **24** is a hollow aspect of the device that directs blood from the inflow orifice **22** to a hollow body **26** of the divola. Blood is further directed from the body **26** of the divola through a hollow outflow tract **28**

to an outflow orifice **30,** where the blood exits the divola. The body **26** of the divola tapers to an apex **32**. The shape and dimensions of the divola **20** mimic the shape and dimensions of the inner aspects of a healthy, nondilated ventricle of a human heart. The inflow tract **24** and the outflow tract **28** are oriented in a three dimensional relationship to the body **26** of the divola in a manner similar to the orientation of the inflow valve and the outflow valve to a ventricle in an undiseased human heart. The body **26** and the apex **32** are flexible and pliable, but these areas of the divola do not stretch. The body **26** and apex **32** easily fill with blood to a predetermined volume or capacity, but they do not fill beyond that volume of capacity. That capacity or normal volume is well known to those skilled in the art. <u>See</u>, <u>e.g.</u>, Arthur C. Guyton, <u>Textbook of Medical Physiology</u>, p. 103 ($8^{th}$ ed. 1991) (Copy of pertinent pages attached). The divola **20** may be made in several sizes to accommodate patients and hearts of different sizes. ('985 Application, pp. 12-13). See also Fig. 15, which shows a partial cross section view of a diastolic volume limiting apparatus **20** in the left ventricle **78** of a heart that has reverse remodeled, during diastole, and Fig. 16, which shows a partial cross section view similar to Fig. 15, but with the heart contracting, in systole.

## <u>VI. Issues</u>

A. Whether Claims 1, 9-11 and 20 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by Noon et al.

B. Whether Claims 1, 5, 8-11, 14-16, 18-21, 29 and 30 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by Corral.

C. Whether Claims 9-11, 18-21 and 30-31 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by Taylor et al.

D. Whether Claim 31 is unpatentable under 35 U.S.C. § 103(a) over Corral.

## VII. Grouping of Claims

The rejected claims do not stand or fall together. Rather, the claims are to be considered in five groups:

1. Claims 1, 5, 10, 20 and 21;
2. Claims 8, 9 and 11;
3. Claims 14-16 and 18-19;
4. Claims 29 and 30; and
5. Claim 31.

## VIII. Argument

Applicant respectfully submits that the rejection of the claims by the Examiner is not well founded in law or fact. The prior art cited by the Examiner does not anticipate the claims under 35 U.S.C. § 102, nor are the claims rendered obvious by the prior art under 35 U.S.C. § 103.

## Summary of Applicant's Contention

The Examiner has missed the point of Applicant's invention and has misinterpreted the pending claim language.

The application concerns a device that limits the blood flow received in the heart, specifically the left ventricle, in order to allow the heart to reverse remodel, or shrink. In a normal heart, when the mitral valve opens, blood flows into the left ventricle. The valve closes and the heart contracts, pumping the blood out of the ventricle. When a heart becomes enlarged, more blood is allowed to enter the ventricle; however, the heart can only contract the same amount and is thus unable to pump all of the blood out of the ventricle. The additional pressure on the walls of the heart chamber further stress the enlarged heart, potentially causing further enlargement. As long as this cycle continues, the heart cannot recover its normal size.

The device of the present invention provides a means for the heart to reverse remodel. The device, referred to in the application as a divola, is the size and shape of a normal, healthy ventricle. It is inserted into the left ventricle so that when blood enters the ventricle, it is contained within the divola. Because the divola will hold only a predetermined capacity or volume of blood, which is the amount of blood that would be held in a normal ventricle, when the heart contracts, it is able to push all the blood out of the ventricle, thus eliminating the problem of excess blood and the related excess pressure on the walls of the heart. By allowing this part of the heart's function to return to normal, stress is taken off the heart and the heart has the opportunity to reverse remodel (i.e., return to normal size).

The predetermined capacity or volume as defined in the present application is not the amount of blood that can be pushed into the sac at the moment before it bursts, which is how it appears that the Examiner is interpreting it. A heart is not capable of continuing to fill the sac of the present invention until it reaches a bursting point. A heart is continually filling and emptying of blood, not constantly pushing more blood into the ventricle or sac until it bursts, as though it were a balloon that a child puts on a water spigot and fills with water until the balloon bursts. Instead, the predetermined capacity or volume is the amount of blood that would be held in a normal ventricle. The device of the present invention is designed so that this predetermined capacity or volume is the amount that the divola can hold easily. If a divola were attached to a fire hose and water was forced into it unceasingly, it might stretch past the predetermined capacity or volume on its way to bursting, but when used in the heart, the bursting point of the divola is irrelevant. It is the predetermined capacity or volume of blood that the heart can push into and out of the divola during each cycle that is relevant as that limitation on the volume is what protects the heart and promotes reverse remodeling.

Although the divola has an important use in the treatment of dilated cardiomyopathy and other forms of chronic dilation of the heart, it has other applications. It may be placed in the heart at the time of a partial left ventriculectomy or after removal of a left ventricular assist device to prevent recurrent dilation of the heart. The divola may also be used for treatment of an ischemic ventricular septal defect to seal the leak between the left and the right ventricles. It may be used to

treat rupture of the left ventricular free wall secondary to acute myocardial infarction. Further, a divola may be placed at the time of a mitral valve replacement. A divola can also be placed in the right ventricle to treat the right heart failure associated with primary pulmonary hypertension.

The references relied on by the Examiner, Noon, Corral and Taylor, do not disclose or teach a flexible sac having a predetermined capacity or volume that can be inserted into a ventricle. The references simply do not meet the limitations of the claims or the purpose of the claimed invention.

**A. The Appealed Claims are not anticipated or obvious because the cited references, individually or in combination, neither disclose nor teach all of the claim limitations.**

1. The 35 U.S.C. § 102 Rejections

In the February 3, 2005 Office Action, the Examiner rejected Claims 1, 9-11 and 20 under 35 U.S.C. § 102 as being anticipated by Noon et al. (4,731,076).

a. Applicable Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 citing Verdegaal Bros. V. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." Id. citing Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Also, "[t]he elements must be arranged as required by the claim..." Id. citing In re Bond, 910 F.2d 831 (Fed. Cir. 1990).

b. Appealed Claims 1, 9-11 and 20 under § 102

The Noon reference relates to a piezoelectric fluid pumping system for use in the human body and more specifically, to a totally or partially implantable fluid delivery system actuated by a valveless piezoelectric drive system. The invention described in the Noon reference is an artificial heart having flexible bladders 10 and 12 which are described as having a size and shape similar to that of a natural heart. The invention further has an outer hydraulic bladders 22 and 24 which are connected to the exterior of the bladders 10 and 12. Outer bladders 22 and 24 contract and release bladders 10 and 12 by means of hydraulic pumps.

The Noon reference does describe an alternate embodiment of the invention for use with a natural human heart. In that embodiment, a hydraulic bladder 54 is connected around the exterior of the natural heart for contracting and releasing the heart in response to the hydraulic pressure.

Nowhere in the Noon reference is there a description of a bladder to be implanted within a natural human heart. The purpose of the invention described in Noon is to drive either an artificial heart or a natural heart. Nowhere does Noon indicate that it will assist in the shrinking or "reverse remodeling" of an enlarged heart.

The Examiner states that the Noon reference discloses "an apparatus fully capable of being inserted into a ventricle of a heart" (February 3, 2005 Office Action, p. 3), however, nothing in the reference itself discloses or even hints at the idea of the device being implanted within the ventricle of a human heart.

Considering first the Noon, *et al.* reference, Applicant respectfully disagrees with the Examiner's contention that Noon anticipates Claims 1, 9-11 and 20. Considering first Claim 1, the claim includes the limitation that the sac is soft and compliant and will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed. Noon simply does not address this issue or the limitations highlighted above. Noon does not express anywhere in his patent the concept of the bladder 10 or 12 being filled to a predetermined volume, and when the bladder has reached capacity, no further filling is allowed. It is readily apparent why Noon does not mention the limitations on the volume of the bladder 10 or 12. Specifically, Noon's bladder 10 and 12 are artificial heart chambers themselves, not sacs inserted into a heart. To the extent that the bladders of Noon might be limited in the volume of blood they would receive, that limitation is as a result of the outer bladder 22 and not as a result of the structure of the bladder 10 or 12.

It is important to appreciate the limitation in the claims that the expansion of the sac of the present invention is limited to a "predetermined" volume. The sac is used to help restore an enlarged heart. For that reason, the sac must be limited to a certain predetermined volume, and after the blood fills the sac to that predetermined volume, no further filling is allowed. Since the bladders of Noon are, in fact, artificial hearts themselves, those bladders could be allowed to expand without a limitation to a predetermined volume. Since the concept of the Noon invention does not in any manner appreciate the need to control the size of the sac, there is no suggestion in

Noon of the structural limitation of Claim 1 of Applicant's invention that the sac be limited to filling a predetermined volume with no further filling being allowed. It is important to understand that it is the sac that controls the extent of filling and not some additional element surrounding the sac as is the case in Noon.

With the present invention, by limiting the filling of the heart with the sac that is inserted into the ventricle, the ventricle will reverse remodel (i.e., shrink in size) to improve the function of the heart. The heart is not replaced by an artificial heart, but rather the sac is used to allow the heart to repair itself by shrinking to an appropriate size. There is no contemplation whatsoever of the artificial hearts 10 and 12 of Noon being of a predetermined capacity or volume and upon reaching that capacity, the sac not expanding so that there can be no further filling of the sac. Noon's bladders or artificial hearts 10-12 do not perform this function, do not have this structure and therefore do not anticipate Applicant's invention as set forth in Claim 1.

Referring now to Claims 9, 10, and 11, the rejection under 35 U.S.C. § 102 based on Noon is again traversed. In each of these claims, the structural limitation with respect to the size of the sac being at a predetermined capacity is simply not suggested or anticipated by Noon. To the extent that the size of the bladders or artificial heart chambers of Noon are limited in size, that limitation is as a result of the outer bladder 22 surrounding the heart. There is no suggestion whatsoever that the structure of the bladder be such that it will have a limited capacity for receiving a predetermined volume of blood.

Of course, it might be acknowledged that any sac that is flexible has a limit on the volume of blood or other liquid that could be placed in the sac. Certainly an amusement balloon would have a limit on the amount of blood that could be put in the balloon before it would explode. However, that size and volume of liquid that could be put in an amusement balloon is not predetermined.

The same argument can be made with respect to Noon. The amount of blood that could be put in the artificial heart of Noon is limited to the extent that there would certainly be a capacity after which the balloon would explode if there was an effort to put an additional volume of blood into the sac, but that volume is unbeknownst to Noon, and Noon does not contemplate establishing on a predetermined basis what that volume would be. Noon certainly does not suggest that when his sac is filled to a predetermined volume, that the size and shape of the sac matches the size and shape of a ventricle of an undiseased human heart. There is simply no suggestion as to what that predetermined capacity is for the Noon artificial heart, nor should there be because Noon is not filling his sac within the ventricle of a human heart and attempting to use that sac in order to reduce the size of an enlarged heart. Noon has no reason to limit the size of his artificial heart sac to the size and shape of an undiseased human heart. That shape could be the size and shape of an enlarged heart and it would not impact Noon's invention. Moreover, there certainly is no suggestion in Noon that the maximum or predetermined volume of blood that can be received in the sac when filled to capacity would cause the sac to appear in the size

and shape to match the size and shape of a ventricle of an undiseased human heart. Therefore, Claim 9 should be allowed over Noon.

Referring to Claims 10 and 11, the same argument can be made that was made in respect to Claim 9. Specifically, there is no suggestion in Noon for filling his artificial heart chambers with blood and limiting the capacity of those chambers to a predetermined amount. There is certainly no suggestion as is set forth in Claim 11 that the predetermined capacity of the bladder or artificial heart of Noon be less than the capacity of the chamber of an enlarged heart. Since Noon is not contemplating the use of his artificial heart device for reducing the size of an enlarged heart, there is no reason for him to make that suggestion, he does not make such a suggestion, and it cannot be reasonably considered that one of ordinary skill in the art would find from Noon a basis from which to suggest limiting the size of his artificial hearts to a predetermined capacity that is smaller than the chamber of an enlarged heart.

Referring next to Claim 20, Applicant respectfully traverses the rejection under 35 U.S.C. § 102 based on the Noon reference. There is no discussion in the Noon reference of limiting to a predetermined amount the volume of blood that is allowed to enter a chamber of a heart in the diastolic phase of the heart function. The Examiner does not even address this specific limitation of Claim 20 in the rejection and it is respectfully submitted that the reason for this oversight is that there is no suggestion for this limitation. Since Noon is addressing a heart problem on a different basis than the Application, there is no reason to think that Noon would suggest limiting to a predetermined amount the volume of blood that is allowed to enter the chamber of a

heart in the diastolic phase of the heart function. Once again, this is the structure of the sac in a defined fashion that distinguishes the sac of Applicant's invention from any other references cited by the Examiner.

c. <u>Appealed Claims 1, 5, 8-11, 14-16, 18-21, 29 and 30 under § 102</u>

The Examiner has rejected Claims 1, 5, 8-11, 14-16, 18-21, 24, 29, and 30 under 35 U.S.C. § 102 as being anticipated by Corral. Applicant respectfully traverses this rejection. Corral contemplates a two-piece ventricular pump that is inserted into either one or both of the heart's ventricles. The two piece device of Corral includes an outer shell typically formed from semi-flexible plastics. The outer shell is then lined with an inner liner 46 into which the blood flows. However, Corral fails to anticipate or suggest Applicant's invention because the Corral device does not include a sac that is soft and compliant and that will fill easily with blood to a predetermined volume, but when said sac is reached to capacity, no further filling is allowed.

Specifically, the structure of the sac of Applicant's invention limits the filling, not a second liner. In the Corral device, the outer shell 44 limits the extent to which the liner 46 can expand. The use of an external device such as the outer shell 44 to limit the ability of the sac to receive a predetermined volume of blood is substantially different from Applicant's invention in which a single element, the sac, limits the volume of blood that can be received in its chamber, and when the sac has reached it capacity as established by the sac, not some outside element, no further filling is allowed. It is the capacity of the sac that limits the amount of blood it receives, not the capacity of the outer shell. Certainly the outer shell does not comply with or meet

the definition of Applicant's invention because that device is described as being made from a semi-flexible plastic, not a soft compliant product that is highly flexible.

Applicant's invention is a substantial improvement over the Corral device because Applicant's invention eliminates the need for a second part and yet accomplishes its goals by using fewer parts while operating with greater efficiently. Applicant's invention is designed to allow an enlarged heart to regenerate itself and remodel to the size of a normal heart. Corral has no such purpose of his device and will not work to do that. For example, looking at column 6 (beginning at line 12) of Corral, the use of the Corral device in an enlarged heart is described. In that particular case, Corral contemplates sizing the external shell 44 to fit the enlarged ventricle and then the diaphragmatic lining can be volumetrically adjusted to ideal diastolic dimension. The alternate structure described in that paragraph likewise does not anticipate Applicant's invention. But as can be seen from the description in Corral just referenced, the Corral device is not intended to assist with the remodeling of an enlarged heart. Corral simply substitutes or inserts the outer shell and liner in the ventricle and allows that ventricle to stay enlarged or continue to enlarge. Thus, Corral would never contemplate using the internal liner with a fixed, predetermined volume capacity that would not expand so as to cause the heart to remodel itself when the invention is used as contemplated by Applicant.

For the reasons indicated, Claim 1 should be allowed over Corral because Corral does not provide a structure that anticipates the claimed structure of Applicant. Nothing in Corral suggests the use of a single sac for insertion in a

ventricle of a heart with the sac being soft and compliant and filling easily with blood to a certain predetermined volume, but when the sac has reached capacity, no further filling is allowed. The sac limits the capacity to receive a certain predetermined volume of blood, not a sac surrounded by a second shell device as is shown in the Corral reference.

Turning now to Claim 5, the rejection of this claim under 35 U.S.C. § 102 based on Corral is also traversed. Again, the method described in Claim 5 contemplates creating a sac of the type described in Claim 1. Inserting that sac into a ventricle of a heart and then connecting the openings in the sac to the valves of the heart or to synthetic valves. Once again, this method contemplates a sac that is used as a stand-alone item that will limit the volume of blood entering the ventricle of the heart to a certain predetermined amount. Corral has no such disclosure. Corral discloses a sac that receives the blood, but a second element, the outer shell, controls or limits the amount of volume of blood that comes within the sac and that is a different structure than the structure described by Applicant. Since Claim 5 is allowable, Claim 8 which depends upon Claim 5, should also be allowable. Moreover, Claim 8 is allowable independently because there is no suggestion in Corral that the liner be a size and shape so that when filled, it will appear generally in size and shape to match the size and shape of a ventricle of an undiseased human heart. Corral simply does not do that. Corral's concept is that the outer shell would be enlarged to meet the size of a diseased human heart ["In dilated hearts ... the IVP's external shell 44 can be sized to

fit the enlarged ventricle ..." Col. 6, ll. 12-15] and the shape and size of the liner is controlled by the filler mechanism, not the structure of the liner.

Referring next to Claim 9, the rejection of this claim based on Corral is also traversed. There is no disclosure that describes the liner of Corral as having a capacity for receiving a predetermined volume of blood and said sac when filled to capacity would appear generally in the size and shape to match the size and shape of a ventricle of an undiseased human heart. There is no predetermined capacity or size for the liner of Corral. The capacity and size of that liner is controlled by the outer shell, not by the flexible sac or liner itself. Moreover, the size and shape of the sac or liner of Corral when filled is unknown because we do not know when it is filled and when it is not filled to its maximum capacity. The maximum amount of blood it can receive may be defined by the outer shell, but that does not mean that the sac has reached its maximum capacity nor does it describe the shape in which the sac would form if it were allowed to filter its maximum capacity. Again, it is the sac that has the predetermined capacity and shape in the Applicant's invention, whereas in Corral, the liner has no predetermined size or shape but rather the size or shape of the liner is controlled by the outer shell.

Claim 10 has also been rejected based on Corral and that rejection is traversed. As has been pointed out in great detail and specificity above, Applicant's sac has a predetermined capacity that limits the amount of blood that can be received in the sac. In Corral, there is no discussion of the capacity of the liner of Corral nor is there any discussion that the liner has a predetermined capacity that limits the amount of blood

that can be received in the liner. Rather, the liner of Corral is a somewhat amorphous product that could be filled to any variable capacity that would have any of a variety of shapes apparently, but for the outer shell that does control to some extent the size and shape of the liner. However, it is not the sac itself that has a predetermined capacity or that limits the amount of blood it can be received in the sac; rather it is the shell that performs those functions and that is different from the invention claimed by Applicant.

With respect to Claim 11, since it depends from Claim 10, it should be allowable because Claim 10 is allowable over the references cited by Examiner. Also, Claim 11 should be allowable on its own independent merit because there is certainly nothing in Corral that discusses that the predetermined capacity of the sac being less than the capacity of the chamber of an enlarged heart. In fact, the contrary is suggested by Corral. Corral suggests that in order to keep the sac from getting bigger, he must make the shell bigger or he must increase the amount of fluid that is pumped into the space between the outer shell and the liner (see Column 6 beginning at line 12). For that reason, Claim 11 should also be allowed.

Turning now to Claims 14, 15 and 16, the rejection of these claims based on Corral is also traversed. Corral does not discuss in any manner a method of reducing stress on the walls of a chamber of a heart by inserting a flexible sac in a chamber of the heart with said sac having a predetermined maximum capacity. Corral talks about a liner that fits within an outer shell. Corral's liner is not described as having any predetermined maximum capacity. The capacity of the liner is limited because of

the outer shell, but that does not mean that the sac itself has a predetermined maximum capacity or certainly does not suggest a maximum capacity that is of a volume that would cause the sac to exert only minimal pressure on the walls of a chamber of the heart. We know the Corral sac is limited in the amount that it can be filled because of the outer shell. However, we do not know what the maximum capacity of the sac itself is and certainly it would appear that since there is a need for an outer shell in the Corral device, the maximum capacity of the liner of Corral would put more than minimal pressure on the walls on the chamber of the heart if the liner were filled to maximum capacity. There is certainly nothing suggested in Corral, as is claimed in Claim 16, that the sac, when filled to maximum capacity, would exert less pressure on the walls on the chamber of the heart than would be exerted if the sac had not been used. It is not the sac in Corral that limits the pressure that is applied to the walls of the chamber of the heart. It is the outer shell and the outer shell is not indicated by the Examiner to be the feature that is being considered as meeting the limitations of Applicant's claims. The Examiner refers to the inner liner as being the part of the disclosure of Corral that the Examiner believes anticipates Applicant's invention. That being the case, it is quite clear that the liner does not perform the function or the steps of the method as described in Claims 14, 15 and 16. For that reason, the rejection of these claims based on Corral should be withdrawn.

Turning now to Claims 18 and 19, these claims have been rejected under 35 U.S.C. § 102 based on Corral, and for the same reasons as been stated with respect to Claims 14-16, Claims 18 and 19 should be allowed. While Corral does use the outer

shell to limit the volume of blood that is allowed to enter the chamber of a heart in the diastolic phase, there is no description in Corral that the predetermined quantity of blood that is allowed to enter the chamber is selected so there is minimal pressure on the walls of the chamber. With respect to Claim 19, the disclosure of Corral does not address any difference between the volume of blood that is allowed to enter the chamber of the heart as between the diastolic phase and the systolic phase. When the chamber of the heart is dilated, the volume of blood that is allowed to enter the outer shell of the Corral device is no different than the amount of blood that is allowed to enter the outer shell when the chamber is in the systolic phase. Furthermore, to the extent that the amount of blood that is in the chamber of the heart when using the Corral device is different that the diastolic and systolic phase, that difference is controlled by the outer shell, not by the liner. Therefore, it is apparent that the limitations of Claims 18 and 19 are not anticipated by the Corral disclosure.

Referring now to Claims 20 and 21, these claims have been rejected under 35 U.S.C. § 102 based on Corral and that rejection is also traversed. The liner of the Corral device does not limit to a predetermined volume the amount of blood that is allowed to enter the chamber of a heart in the diastolic phase of the heart function. It is the outer shell that provides that limitation, and the flexible sac (the inner liner that the Examiner refers to) does not limit the volume of blood that is allowed to enter the chamber of the heart in the diastolic phase. With respect to Claim 21, Corral does not disclose a method of treating a diseased heart by inserting a flexible sac into the chamber of the heart with the sac limiting to a predetermined volume the amount of

blood that is allowed to enter the chamber in the diastolic phase of the heart function. It is the outer shell that limits the amount of blood that is allowed to enter the chamber of the heart in the diastolic phase in Corral, not the liner. For these reasons, Claims 20 and 21 should be allowed.

Referring next to Claims 29 and 30, these claims have been rejected based on Corral either under 35 U.S.C. § 102. Applicant respectfully traverses these rejections. The methods described in Claims 29 and 30 are similar to the methods of Claims 32, 33, and 34. Again, these methods all contemplate treatment of heart disorders by inserting the sac of Claim 20 in the heart and connecting the sac to the annulus of the inflow and outflow valves of the chamber. Applicant respectfully submits that the method of reducing the likelihood of an enlargement of a cardiac chamber by inserting the sac of Claim 20 in the heart and connecting the sac to the annulus of the inflow valve and the annulus of the outflow value of the chamber is not suggested by Corral either as a stand-alone feature or as an addition to a conventional operation on the heart. There is no suggestion whatsoever of this methodology in Corral. Likewise, there is no suggestion in Corral of a method of treating a left ventricular aneurysm by inserting the sac of Claim of 20 in the left ventricle of the heart in addition to a step of conventional operative repair of a left ventricular aneurysm. There is no suggestion whatsoever of using the sac of Claim 20 to either reduce the likelihood of heart enlargement either as a stand-alone item or as an additional feature to conventional treatment of these maladies of the heart. Corral does not make that suggestion and the rejection of Claims 29 and 30 is respectfully submitted, should be withdrawn.

d. Appealed Claims 9-11, 18-21 and 30-31 under § 102(b)

The Examiner rejected Claims 9-11, 18-21 and 30 and 31 under 35 U.S.C. § 102(b) as being anticipated by Taylor, *et al* (U.S. 2002/0169360 A1). Applicant respectfully suggests that the disclosure of Taylor does not anticipate the claims.

With reference to Claims 9-11, the Taylor reference does not disclose a flexible sac having a capacity for receiving a predetermined volume of blood, which sac, when filled to capacity, would appear in size and shape to match generally the size and shape of the ventricle of an undiseased human heart.

First, the Taylor sac is not filled with blood. Nothing in the Taylor reference discloses filling the sac with blood. Instead, the sac is filled with "inflation fluids" (i.e., saline or water) (see page 9, paragraph 86 of the Taylor reference).

Second, nothing in the Taylor reference discloses a sac with a predetermined volume or capacity. Claims 9-11 claim a sac with a predetermined volume. In the Taylor reference, the volume to which the sac is filled is clearly determined by the surgeon, who decides how much to expand the sac after it is inserted (see page 9, paragraphs 87-88), not by the capacity of the sac itself. While the Taylor sac might have a limit on the volume of fluid it can hold in the sense that the surgeon could fill it until it burst, that is completely different from the sac with a predetermined volume of the present invention, wherein the predetermined volume is a limit on the amount of blood that can be pumped into the sac by the heart. The heart pumps the predetermined amount of blood into the sac and then the sac does not allow the heart to pump anymore blood in. The blood is then pushed out of the sac and the cycle

begins again. The predetermined volume refers to the amount of blood that can healthily and safely be pumped into the ventricle during one cycle. Limiting the capacity of the sac to this predetermined volume protects an enlarged heart and offers it the opportunity to reverse remodel, or heal itself, by shrinking from its enlarged state. Nowhere in Taylor is there a suggestion to fill the sac with a predetermined amount of blood.

Finally, when the sac 113 of the Taylor invention is filled, it simply takes up volume in the ventricle of an enlarged heart; Taylor does not disclose a sac that matches the size and shape of an undiseased human heart.

The Taylor sac is never filled with blood; rather it is filled with saline fluid, water, or other well-known inflation fluid (see page 9, paragraph 86 of the Taylor reference). The sac of Taylor also does not have a predetermined volume or capacity. There is no suggestion whatsoever in Taylor that the sac has a predetermined volume. Moreover, there is no suggestion that the Taylor sac is filled with blood once inserted into the chamber of a heart, and in fact, the sac does not receive the blood; rather, it is simply for the purpose of reducing the ventricular space of an enlarged heart. This is contrary to Applicant's invention, which receives and controls the blood flowing into the ventricle to a predetermined volume.

The rejection of Claims 18-21 based on Taylor is also inappropriate and unfounded and should be withdrawn. The methods of Claims 18 through 21 involve the treatment of a diseased heart and the process for the treatment of a diseased heart that involves the insertion of a flexible sac into a chamber of the heart with the sac

limited to a predetermined volume of the amount of blood that is allowed to enter the chamber of the heart. The sac of Taylor reduces the amount of volume of blood that is allowed to enter the chamber of the heart, but it does not limit it to a predetermined volume because the walls of the heart could expand under pressure and therefore cause the heart chamber to continue to receive more and more blood as the heart enlarges. Furthermore, the device of Taylor does not minimize the pressure on the walls of the heart chamber; rather, it is more likely the device of Taylor would increase the pressure on the walls of the heart chamber. The sac of the present invention keeps the blood entering the ventricle contained, so that it does not press on the walls of the heart chamber.

With respect to Claims 30 and 31, there is no suggestion whatsoever in Taylor for a method of reducing the likelihood of enlargement of a cardiac chamber by inserting a sac such as the one claimed in Claim 20 in the chamber of the heart in addition to a conventional operation of the heart; or as an additional step to the conventional operative repair of a left ventricular aneurysm. Taylor only contemplates using his invention once the heart is enlarged, not as a method of controlling the likelihood of the enlargement of the heart. In fact, Taylor's invention would only work once the heart is enlarged because he inserts a sac into the enlarged chamber of the heart and blows the sac up so that it reduces the remaining volume in the chamber of the heart. If the heart was not enlarged, there would be no additional volume in the ventricle to reduce. Conversely, Applicant's invention is a sac inserted into the chamber of the heart with the blood flowing into the sac to limit and control

the amount of blood that goes into the chamber so that the pressure of the blood will not cause the heart to enlarge. There is no suggestion in Taylor of using the sac described in his patent as an addition to the step of the conventional operative repair of a left ventricular aneurysm. In fact, Taylor's device could not function in that manner. If there were an aneurysm of the left ventricle, placing the Taylor sac into the heart to take up volume would only increase the pressure at the point of damage where the aneurysm has occurred and be more likely to cause serious additional damage to the patient if not death. Applicant's invention on the other hand, receives the blood into the sac so that even if there is an aneurysm of the heart's left ventricular chamber, the pressure of the blood coming into the chamber does not increase the likelihood of further tearing at the point where the aneurysm has already occurred.

For these reasons, it is respectfully submitted the Claims of 30 and 31 are patentable over Taylor and Taylor does not anticipate the invention as claimed in these claims.

2. The 35 U.S.C. § 103 Rejections

a. Applicable Law

A rejection for obviousness is to be analyzed under 35 U.S.C. § 103 and Graham v. John Deere Co., 383 U.S. 1, 148 U.S.P.Q. 459 (1966). Tenets of patent law under the statute and the Graham case are summarized in Hodosh v. Block Drug Co., 786 F.2d 1136, 1143 n. 5, 229 U.S.P.Q. 182, 187 n. 5 (Fed. Cir. 1986), cert.

denied, 479 U.S. 827, 107 S.Ct. 106, 93 L.Ed.2d 55 (1986). These tenets include the following.

Obviousness cannot be established by using hindsight. As the Court of Appeals for the Federal Circuit said in Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 679, 7 U.S.P.Q.2d 1315, 1318 (Fed. Cir. 1988), "[w]hen determining obviousness, '[t]he invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time." In In re Sponnoble, 405 F.2d 578, 585, 160 U.S.P.Q. 237, 243 (C.C.P.A. 1969), the Court of Customs and Patent Appeals said, "[t]he court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is, we must view the prior art without reading into that art appellant's teachings."

Each claim must be read as a whole and interpreted in light of the specification. This includes a consideration of properties or advantages of the claimed invention. In re Dillon, 919 F.2d 688, 697-98, 16 U.S.P.Q.2d 1897, 1905 (Fed. Cir. 1990); In re Lintner, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (C.C.P.A. 1973); In re Papesch, 315 F.2d 381, 391, 137 U.S.P.Q. 43, 51 (C.C.P.A. 1963); see also, In re Ruschig, 343 F.2d 965, 978-79, 145 U.S.P.Q. 274, 285-86 (C.C.P.A. 1965).

Cited references must make it obvious to do the claimed invention, not merely obvious to try. This requires a showing or suggestion of motivation to make a combination of separately disclosed elements. The Court of Appeals for the Federal Circuit has stated, "[t]his court ... reaffirms that structural similarity between claimed and prior art subject matter, proved by combining references or

otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness...." In re Dillon, 919 F.2d 688, 697, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990). When such reason or motivation is missing, there is no *prima facie* case of obviousness. There must be factual evidence and specific objective reasoning, not mere conclusory statements, as to this and the other elements to establish *prima facie* obviousness. In re Lee, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002).

Additionally, a *prima facie* case of obviousness exists when three basic criteria are met. Briefly, there must be some suggestion or motivation to combine reference teachings, a reasonable expectation of success must exist, and the combined reference teachings must teach or suggest all of the claim limitations. It is impermissible to use the claims as a framework from which to pick and choose among individual references to recreate the claimed invention. In re Fine, 5 U.S.P.Q.2d 1596, 1598-9 (Fed. Cir. 1988). Moreover, the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." In re Fritch, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). The mere fact that a prior art structure could be modified to produce the claimed invention would not have made the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In order to determine the patentability of a claim, while judging that claim against the prior

art, all words of the claim must be considered. <u>In re Wilson</u>, 424 F.2d 1382, 165 U.S.P.Q. 494 (C.C.P.A. 1970).

b. <u>Appealed Claim 31 under § 103</u>

In the Final Office Action, the Examiner rejected Claim 31 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Corral (5,139,517). Applicant believes this rejection lacks any basis in law or in fact and in fact, finds the rejection somewhat confusing. Accordingly, Applicant believes the rejection should be withdrawn.

The Examiner's rejection states "Corral teaches the apparatus as described the grounds of rejection above, however, is unclear if an outflow valve is used. It would have been obvious to one having ordinary skill in the art to have utilized an outflow valve in combination with said apparatus if the natural valve was damaged or deemed unsatisfactory by the surgeon." In addition to the lack of clarity present in the first sentence quoted above, Claim 31 does not include a valve of any kind, so it is not clear how the Examiner's comments apply to Claim 31.

The Examiner continues: "[r]egarding claim 31, Corral teaches the apparatus can be used when *'the natural heart may become incapable of maintaining adequate circulation because of various disease processes, including myocardial infarction.'* It is well know (sic) in the art that this teaching includes left ventricular aneurysm." (emphasis in original).

The method described in Claim 31 is similar to the methods of allowed Claims 32, 33, and 34. Again, these methods all contemplate treatment of heart disorders by

inserting the sac of Claim 20 in the heart and connecting the sac to the annulus of the inflow and outflow valves of the chamber. Applicant respectfully submits that there is no suggestion in Corral of a method of treating a left ventricular aneurysm by inserting the sac of Claim of 20 in the left ventricle of the heart in addition to a step of conventional operative repair of a left ventricular aneurysm and that it would not be obvious to one of skill in the art to adapt Corral to reach the invention claimed in Claim 31.

Finally, the Examiner states that "[r]egarding the limitation 'an addition to a conventional operation', which could include exploratory procedures which are inherently done." Nowhere does the Examiner particularly identify any suggestion, teaching, or motivation to combine the prior art references, nor does the examiner make specific findings concerning the level of ordinary skill in the art, the nature of the problem to be solved, or other findings to support a proper obviousness analysis. The Examiner has simply pulled a phrase from thin air and asserted that it would be obvious to combine the procedure with exploratory surgery, which is not at all obvious to Applicant, since the method claimed in Claim 31 is well beyond the scope of exploratory surgery. There is no suggestion whatsoever of using the sac of Claim 20 to treat a left ventricular aneurysm either as a stand-alone item or as an additional feature to conventional treatment of these maladies of the heart. Corral does not make that suggestion and the rejection of Claim 31, it is respectfully submitted, should be withdrawn.

## B. Grouping of the Claims.

The claims have been separated into five groupings, with each grouping separately patentable. The basis for this assertion is discussed in detail in the argument above.

Group I includes Claims 1, 5, 10, 20 and 21 are separately patentable from the other appealed claims. These claims are directed to a flexible sac for insertion in a chamber of the heart for limiting to a predetermined volume the amount of blood entering the chamber. Claims 1, 20 and 21 are additionally limited with the claimed feature that the limitation occurs during the diastolic phase of heart function.

Group II includes Claims 8, 9 and 11 are separately patentable because they are directed to a sac having a predetermined volume which sac is the size and shape of the ventricle of an undiseased human heart. For this reason, Applicant believes the Board should consider Claims 8, 9 and 11 separately from the other claims.

Group III includes Claims 14-16 and 18-19 which are directed to a sac having a predetermined volume which is inserted into a chamber of a heart and which include the additional function of reducing stress on the walls of the heart chamber.

Group IV includes Claims 29 and 30 which are directed to a method of reducing the likelihood of enlargement of a cardiac chamber by inserting a sac having a predetermined volume limit into a cardiac chamber.

Group V includes Claim 31 which is directed to a method of treating a left ventricular aneurysm by inserting a sac having a predetermined volume into the left ventricle of a heart.

## Conclusion

Appellant has established that the Noon, Corral and Taylor references do not disclose or teach a device or method for an apparatus having a flexible sac that can be inserted into the ventricle of a heart and will fill with blood to a predetermined volume and when it has reached that volume, no further filling is allowed. For the foregoing reasons, Appellant respectfully asserts that the claim rejections should be reversed and that a Notice of Allowance should issue.

Respectfully submitted,

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## IX. Appendix of Claims

1. (original) A diastolic volume limiting apparatus for insertion into a ventricle of a heart, including

a. a hollow plastic sac with two openings,

b. said sac being soft and compliant so that it will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed.

5. (original) A method of treating a diseased heart including the steps of:

a. creating a hollow plastic sac with two openings, said sac being soft and compliant so that it will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further expansion is allowed;

b. inserting said sac into a ventricle of a heart;

c. connecting one of said openings in said sac to the annulus of the inflow valve of the ventricle; and

d. connecting the other of said openings in said sac to the annulus of the outflow valve of the ventricle.

8. (original) The method of claim 5 including the additional steps of forming the sac so that when the sac is filled to capacity, it will appear generally in

size and shape to match the size and shape of a ventricle of an undiseased human heart.

9. (original) A flexible sac for placement in a ventricle of a heart, said sac having a capacity for receiving a predetermined volume of blood, and said sac, when filled to capacity, appears generally in size and shape to match the size and shape of a ventricle of an undiseased human heart.

10. (original) A flexible sac for insertion in a chamber of a heart, said sac having a predetermined capacity that limits the amount of blood that can be received in said sac.

11. (original) The sac of claim 10 wherein said predetermined capacity is less than the capacity of the chamber of an enlarged heart.

14. (original) A method of reducing stress on the walls of a chamber of a heart by inserting a flexible sac in a chamber of the heart, said sac having a predetermined maximum capacity, and connecting the sac to the annulus of the inflow valve and to the annulus of the outflow valve of the chamber.

15. (original) The method of claim 14 wherein said sac, when filled to said maximum capacity, exerts only minimal pressure on the walls of a chamber of the heart.

16. (original) The method of claim 14 wherein said sac, when filled to said maximum capacity, exerts less pressure on the walls of a chamber of the heart than would be exerted if the sac had not been used.

18. (original) A method of reducing stress on the walls of a chamber of a heart by limiting to a predetermined quantity the volume of blood that is allowed to enter the chamber in the diastolic phase of the heart function, and the predetermined quantity is selected so that there is minimal pressure on the walls of the chamber.

19. (original) A method of reducing stress on the walls of a chamber of a heart by limiting to a predetermined amount the volume of blood that is allowed to enter the chamber in the diastolic phase of the heart function.

20. (original) A flexible sac for insertion in a chamber of the heart, said sac limiting to a predetermined amount the volume of blood that is allowed to enter the chamber in the diastolic phase of the heart function.

21. (original) A method of treating a diseased heart by inserting a flexible sac in a chamber of the heart, said sac limiting to a predetermined volume the amount of blood that is allowed to enter the chamber in the diastolic phase of the heart function.

29. (original) A method of reducing the likelihood of enlargement of a cardiac chamber by inserting the sac of claim 20 in the heart and connecting the sac to the annulus of the inflow valve and to the annulus of the outflow valve of the chamber.

30. (original) A method of reducing the likelihood of enlargement of a cardiac chamber by inserting the sac of claim 20 in a chamber of the heart, as an addition to a conventional operation of the heart.

31. (original) A method of treating a left ventricular aneurysm by inserting the sac of claim 20 in the left ventricle of the heart, as an addition to or step of a conventional operative repair of a left ventricular aneurysm.

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# Textbook of MEDICAL PHYSIOLOGY

## Eighth Edition

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***Period of Ejection.*** When the left ventricular pressure rises slightly above 80 mm Hg (and the right ventricular pressure slightly above 8 mm Hg), the ventricular pressures now push the semilunar valves open. Immediately, blood begins to pour out of the ventricles, with about 70 per cent of the emptying occurring during the first third of the period of ejection and the remaining 30 per cent during the next two thirds. Therefore, the first third is called the *period of rapid ejection* and the last two thirds the *period of slow ejection*.

For a very peculiar reason, the ventricular pressure falls to a value slightly *below* that in the aorta during the period of slow ejection, despite the fact that some blood is still leaving the left ventricle. The reason is that the blood flowing out of the ventricle has built up momentum. As this momentum decreases during the latter part of systole, the kinetic energy of the momentum is converted into pressure in the aorta, which makes the arterial pressure slightly greater than the pressure inside the ventricle.

**Period of Isovolumic (Isometric) Relaxation.** At the end of systole, ventricular relaxation begins suddenly, allowing the intraventricular pressures to fall rapidly. The elevated pressures in the distended large arteries immediately push blood back toward the ventricles, which snaps the aortic and pulmonary valves closed. For another 0.03 to 0.06 second, the ventricular muscle continues to relax, even though the ventricular volume does not change, giving rise to the period of *isovolumic* or *isometric relaxation.* During this period, the intraventricular pressures fall rapidly back to their very low diastolic levels. Then the A-V valves open to begin a new cycle of ventricular pumping.

**End-Diastolic Volume, End-Systolic Volume, and Stroke Volume Output.** During diastole, filling of the ventricles normally increases the volume of each ventricle to about 110 to 120 milliliters (ml). This volume is known as the *end-diastolic volume.* Then, as the ventricles empty during systole, the volume decreases about 70 ml, which is called the *stroke volume output.* The remaining volume in each ventricle, about 40 to 50 ml, is called the *end-systolic volume.* The fraction of the end-diastolic volume that is ejected is called the *ejection fraction*—usually equal to about 60 per cent.

When the heart contracts strongly, the end-systolic volume can fall to as little as 10 to 20 ml. On the other hand, when large amounts of blood flow into the ventricles during diastole, their end-diastolic volumes can become as great as 150 to 180 ml in the normal heart. And by both increasing the end-diastolic volume and decreasing the end-systolic volume, the stroke volume output can at times be increased to about double normal.

## FUNCTION OF THE VALVES

**The Atrioventricular Valves.** The *A-V valves* (the *tricuspid* and the *mitral* valves) prevent backflow of blood from the ventricles to the atria during systole, and the *semilunar valves* (the *aortic* and *pulmonary* valves) prevent backflow from the aorta and pulmonary arteries into the ventricles during diastole. All these valves, which are illustrated in Figure 9-6, close and open *passively*. That is, they close when a backward pressure gradient pushes blood backward, and they open when a forward pressure gradient forces blood in the forward direction. For obvious anatomical reasons, the thin, filmy A-V valves require almost no backflow to cause closure, whereas the much heavier semilunar valves require rather strong backflow for a few milliseconds.

**Function of the Papillary Muscles.** Figure 9-6 also illustrates the papillary muscles that attach to the vanes of the A-V valves by the *chordae tendineae.* The papillary muscles contract when the ventricular walls contract, but, contrary to what might be expected, they *do not* help the valves to close. Instead, they pull the vanes of the valves inward toward the ventricles to prevent their bulging too far backward toward the atria during ventricular contraction. If a chorda tendinea becomes ruptured or if one of the papillary muscles becomes paralyzed, the valve bulges far backward, sometimes so far that it leaks severely and results in severe or even lethal cardiac incapacity.

**The Aortic and Pulmonary Valves.** There are differences between the operation of the aortic and pulmonary valves and that of the A-V valves. First, the high pressures in the arteries at the end of systole cause the semilunar valves to snap to the closed position in comparison with a much softer closure of the A-V valves. Second, because of smaller openings, the velocity of blood ejection through the aortic and pulmonary valves is far greater than that through the much larger A-V valves. Also, because of the rapid closure and rapid ejection, the edges of the semilunar valves are subjected to much greater mechanical abrasion than are the A-V valves, which also are supported by the chordae tendineae. It is obvious from

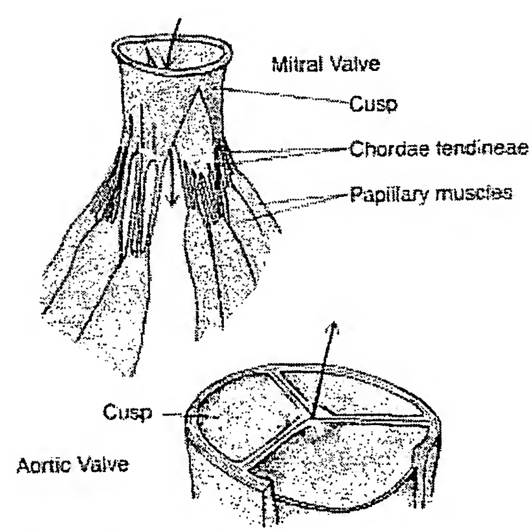


**Figure 9-6.** Mitral and aortic valves.